

Subsequent Entry Biologics (SEBs) First Principles

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The emergence of SEBs in the Canadian market has led the pan-Canadian Pharmaceutical Alliance (pCPA) to begin developing principles to guide more consistent negotiations for these products and related reference biologics, as the pCPA works towards establishment of a SEB policy framework.

The following first principles will guide the pCPA approach to negotiations on SEBs and reference biologics:

- All SEB and reference biologic manufacturer proposals will only be considered through the **national pCPA negotiation process** rather than individual or selected jurisdictions. Determination of whether or not to proceed with negotiations with the requesting manufacturer will be made at the discretion of the pCPA.
- Products under consideration by the pCPA will be informed by Health Canada's regulatory determinations (that the SEB products are safe and efficacious with no clinically meaningful differences with the comparator reference drugs), Health Technology Assessment recommendations, and/or other **evidence** or considerations as available.
- Consistent with its mandate that includes increasing patient access to clinically and cost-effective drug treatment options, the pCPA will encourage a competitive environment that includes SEB market growth and is conducive to **long-term cost reductions** and sustainability for public drug plans.
- The introduction of an SEB must provide a reduction in the drug's **transparent price** to benefit all Canadians.
- Proposals from reference biologic manufacturers will only be considered if they:
 - Provide overall national **value** to public drug plans and do not result in **incremental costs** to individual jurisdictions; and
 - Provide at least similar overall **value** compared to the SEB, and must include similar or better transparent price reductions if **equivalent listing status** is sought.

These first principles are a starting point and are expected to evolve through the pCPA's engagement with stakeholders, including the pharmaceutical industry, to develop a more comprehensive SEB policy framework.